NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AVENTIS PHARMACEUTICALS INC., MARRELL PHARMACEUTICALS INC., and CARDERM CAPITAL L.P., Plaintiffs, v. IMPAX LABORATORIES, INC., *et al.*, Defendants.	Civil Action Nos. 02-1322 (GEB) 03-1179 (GEB) 03-1180 (GEB) 03-5108 (GEB) 03-5829 (GEB) 04-1075 (GEB) 04-1076 (GEB) 04-1077 (GEB) 04-1078 (GEB) 04-2305 (GEB) 04-3194 (GEB) 05-4255 (GEB) 06-5463 (GEB) 07-5054 (GEB) 07-5180 (GEB) 09-0325 (GEB) 09-4638 (GEB) 09-5179 (GEB) 10-1471 (GEB) **MARKMAN OPINION** **PUBLIC REDACTED VERSION**

BROWN, Chief Judge

This matter comes before the Court on the parties' request for claim construction in a *Markman* hearing. The parties submitted their opening *Markman* briefs on September 2, 2010, and their responsive briefs on October 14, 2010. (Doc. Nos. 214, 215, 216, 219, 260, 262, 265, 267).[1] The Court held a *Markman* hearing on November 10, 2010.

I. Background

This is a consolidated patent infringement case involving the pharmaceutical fexofenadine. Before the Court is the parties' request for claim construction in a *Markman* hearing. There are nine (9) patents at issue and twenty-nine (29) different disputed claim terms.

[1] All docket citations are to the 09-4638 case because several of the other dockets do not contain every document that the parties submitted.

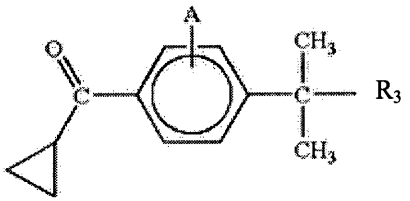
Three of the patents are the "Method Patents" – United States Patent Numbers 6,037,353 (the "'353 patent"), 6,187,791 (the "'791 patent"), and 6,399,632 (the "'632 patent"). These patents share an identical specification and their claims are directed to administering fexofenadine to slightly different populations of people. Four of the patents are directed to fexofenadine formulations; these are United States Patent Numbers 6,039,974 (the "'974 patent"), 5,855,912 (the "'912 patent"), 6,113,942 (the "'942 patent"), and 5,738,872 (the "'872 patent"). The '942 and '912 patents share a written description. Finally, two of the patents are directed towards the process of making piperidine derivatives; they are United States Patent Numbers 7,390,906 (the "'906 patent") and 5,750,703 (the "'703 patent"). These patents also share a substantially identical written description.

On November 10, 2010, this Court conducted a *Markman* hearing. At the hearing, the Court construed eleven (11) of the twenty-nine (29) terms for the reasons it set forth on the record. In addition to those eleven (11) terms, the parties agreed that three (3) terms from the '906 patents were no longer relevant to the asserted claims and conferred to arrive at a construction for the term "wet granulation" in the '872 patent. These rulings resolved all of the claim construction issues in the '353, '912, '942, and '872 patents. The Court reserved its ruling on the remaining fourteen (14) terms; these terms consist of all five (5) terms from the '791 and '632 patents, four (4) terms from the '974 patent, two (2) terms from the '703 patent, and three (3) terms from the '906 patent.

This opinion addresses only the five (5) outstanding terms from the '703 and '906 patents. These patents share a written description because they stem from the same patent application. Both patents claim a process by which fexofenadine and other piperidine derivatives may be formulated.

The five (5) terms that this Court must construe involve the parties' dispute over the purity of the piperidine derivative as well as an intermediate regioisomer ("para-CPK") used to create the piperidine derivative in the two patents. They are:

(1) "substantially pure regioisomer of the following formula



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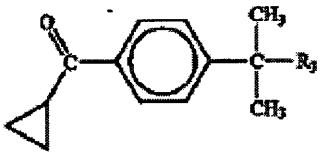
from claim 1 of the '703 patent; the Court will refer to formula depicted as the "para-CPK" intermediate regioisomer;

(2) "substantially pure," which is part of the first term in claim 1 of the '703 patent;

(3) "regioisomer of the following formula



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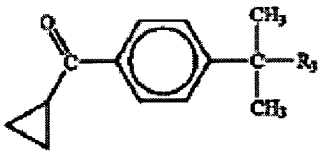
from claim 1 of the '906 patent;

(4) "providing a regioisomer of the following formula:



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from the same portion of claim 1 of the '906 patent as the third term, but including additional context;

(5) "piperidine derivative," from claims 1, 6, 7, 8, and 9 of the '906 patent.

(Joint Claim Construction Chart ("JCC") at 35-39, 49-52; Doc. No. 210-1). The Court will address the terms implicated in the other patents in separate opinions.

II. Discussion

A. Standard of Review

The first step in a patent infringement analysis is to define the meaning and scope of the claims of the patent. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996). Claim construction, which serves this purpose, is a matter of law exclusively for the court. *Id.* at 979. The focus of a court's claim construction analysis must begin and remain on the language of the claims, "for it is that language that the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112, ¶ 2).

Generally, there is a presumption that the words of a claim will receive the full breadth of their ordinary meaning. *NTP, Inc. v. Research In Motion, Ltd.*, 392 F.3d 1336, 1346 (Fed. Cir. 2004). The ordinary meaning may be derived from a variety of sources; including intrinsic evidence, such as the claim language, the written description, drawings, and the prosecution history; as well as extrinsic evidence, such as dictionaries, treatises, or expert testimony. *Id.*

When determining the meaning of the terms, the court must primarily consider the intrinsic evidence, including the specification and prosecution history. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996). The specification "is the single best guide to the meaning of a disputed term." *Id.* at 1587. However, it is improper to import limitations from the specification into the claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1320, 1323 (Fed. Cir. 2005); *Resonate Inc. v. Alteon Websystems, Inc.*, 338 F.3d 1360, 1364-65 (Fed.

Cir. 2003). Courts "should also consider the prosecution history of the asserted patents" because it "can inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution." *Telcordia Techs., Inc. v. Cisco Sys.*, 612 F.3d 1365, 1372 (Fed. Cir. 2010); *Phillips*, 415 F.3d at 1317. Courts should, however, grant the communications in the prosecution history less weight than the specification because they are negotiations and "often lack[] the clarity of the specification." *Phillips*, 415 F.3d at 1317.

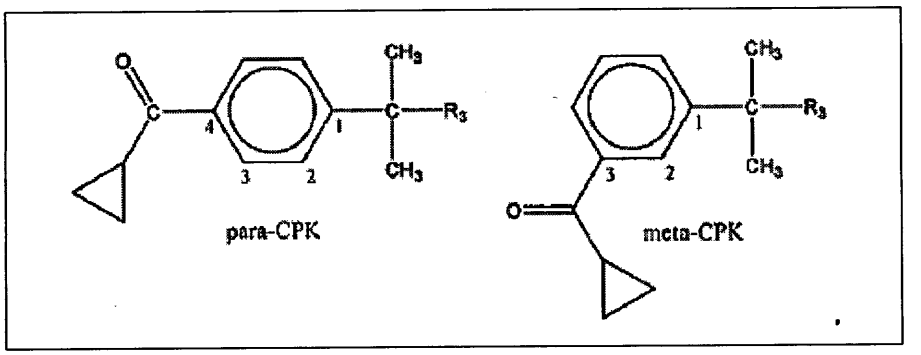
In addition to the specification and prosecution history, a court may also consider extrinsic evidence to determine the meaning of a term when an analysis of the intrinsic evidence alone does not resolve the ambiguities of a disputed claim term. *Vitronics Corp.*, 90 F.3d at 1582-83.

The presumption of ordinary meaning may be rebutted if the patentee acted as his or her own lexicographer by clearly setting forth a definition of the claim term unlike its ordinary and customary meaning. *Brookhill-Wilk I, LLC. v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298-99 (Fed. Cir. 2003). The patentee's intent to define the term must be clear before the court will use it to redefine the term and impose limits on the ordinary meaning. *Merck & Co, Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1370 (Fed. Cir. 2005).

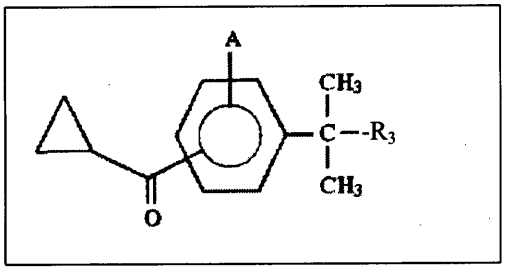
When the patentee has not provided an explicit definition of a claim term, the words of a claim are given their plain and ordinary meaning to a person of ordinary skill in the art. *Vitronics*, 90 F.3d at 1582. The person of ordinary skill in the art is deemed to have read the claim terms in the context of the entire patent, including the specification. *Phillips*, 415 F.3d at 1313.

B. Analysis

The '703 and '906 patents claim a process of creating fexofenadine and other piperidine derivatives through a chemical reaction. The Background of the Invention explains the problem in the art that the patent solved. It is directed toward the difficulties with the prior art Carr process of creating fexofenadine with a Friedel-Crafts reaction. ('703 patent, 1:55-4:25). According to the Background, the problem with that process is that none of the intermediates or the final product is a sufficiently pure para-regioisomer, and cannot be purified of the meta-isomer. (*Id.*). Only para-regioisomers of this type of reaction are pharmaceutically advantageous, and so the purity of the regioisomers and derivatives is an important consideration. As a result, the patentee's process converts one of the intermediates into CPK, which can then be purified of meta-CPK to become pure para-CPK. The difference between the para-CPK and the meta-CPK (and all para and meta regioisomers) is the position of the bond on the ring; the para-CPK bonds to the fourth site, whereas the meta-CPK bonds to the third site:



The convention in the art is that when the drafter is referring to a mixture of the two, he will extend the line that signifies the bond inside the ring to show that both para- and meta-CPK are present. In this instance, the formula for the mixture would look like:



The patentee, Dr. D'Ambra testified to this distinction. (D'Ambra Dep. at 92).

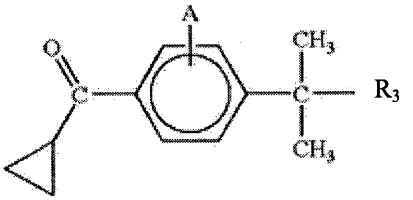
The relevant claims of the patents are similar, but not identical. Claim 1 of the '703 patent requires the para-CPK used in the reaction to be "substantially pure" but does not put the same requirement upon the final-product piperidine derivatives (which include fexofenadine). ('703 patent, 24:8). Claim 1 of the '906 patent claims a very similar process of formulating fexofenadine and other piperidine derivatives; however, the claim does not use the words "substantially pure" to modify either the para-CPK intermediate or the ultimate piperidine product. ('906 patent, 22:33-23:15). The other difference between the claims is that the '906 patent is drawn to a more limited set of piperidine derivative final products. The '906 patent is drawn only to derivatives with rings made up of hydrogen substituents (i.e. benzene rings), not the more general aromatic rings that are claimed in the '703 patent. (*Compare* '703 patent, 23:45-24:6, *with* '906 patent, 22:33-58).

Both patents share substantially identical written descriptions because they are divisional children of the same application. ('703 patent, Related U.S. Application Data; '906 patent, Related U.S. Application Data). Several other patents issued from the same application, including U.S. Patent No. 5,578,610 patent ("the '610 patent"), which was a divisional of the '703 patent application, but issued prior to the '703 patent. ('610 patent, Related U.S. Application Data, Date of Patent). The '610 patent also shares a substantially identical written description.

1. Terms in the '703 patent

At issue in the '703 patent are the terms:

(1) "substantially pure regioisomer of the following formula



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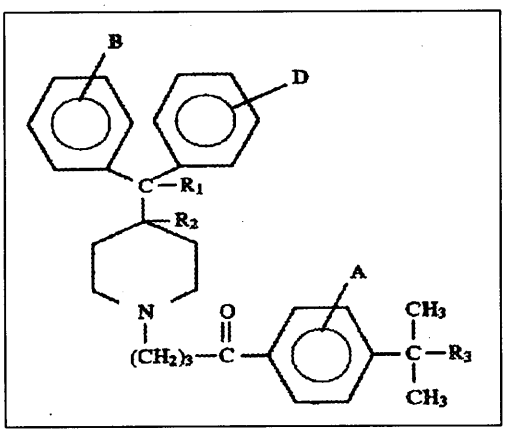
from claim 1 of the '703 patent; and

(2) "substantially pure," which is part of the first term in claim 1 of the '703 patent.

(JCC at 35-37). Claim 1, which contains these terms, provides:

1. A process of preparing a piperidine derivative compound of the formula:



wherin

R_1 is hydrogen or hydroxyl;

R_2 is hydrogen;

or R_1 and R_2 taken together form a second bond between the carbon atoms bearing R_1 and R_2;

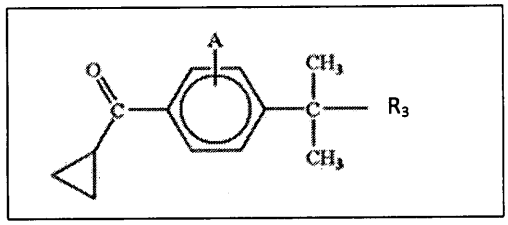
R_3 is – COOH or – $COOR_4$;

R_4 has 1 to 6 carbon atoms;

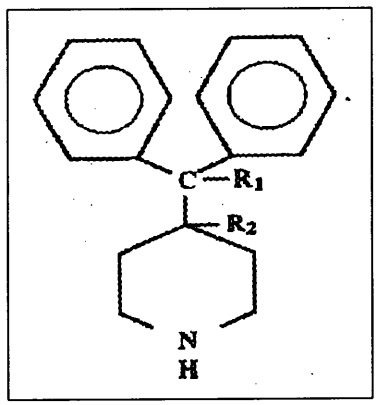
A, B, and D are the substituents of their aromatic rings, each of which may be different or the same, and are selected from the group consisting of hydrogen, halogens, alkyl, hydroxyl, alkoxy, or other substituents,

said process comprising;

providing a *substantially pure regioisomer of the following formula:*



converting the regioisomer to the piperidine derivative compound with a piperidine compound of the formula:



('703 patent, 23:45-24:34) (emphasis on disputed term). The final product in this process is a piperidine derivative; one of these derivatives is fexofenadine, an active ingredient in the Allegra formulations that Plaintiffs market.

The parties disagree on which elements of this term should be construed. Defendants argue that "substantially pure" should be construed and then use the prosecution history of this and related patents to show that the patentee used "substantially pure" to mean 98% purity. (Defs.' Br. at 52-63). Plaintiffs argue that the term must be construed in context, that "substantially pure" in context of the para-CPK intermediate means something different than when it is used in the context of the final product. Plaintiffs argue that the prosecution history showing "substantially pure" to mean 98% purity is not relevant because that purity referenced only the final product – the piperidine derivative – and not the purity of the para-CPK. (Pls.' Br. at 76-84; Pls.' Resp. Br. at 61-67, 69-79). Thus, Plaintiffs recommend a generic definition, that "substantially pure regioisomer" means "largely but not wholly the para regioisomer of the

cyclopropyl ketoester or ketoacid intermediate of the structure shown in the formula, as compared to the meta-isomer[.]" (JCC at 35).

This Court finds that the prosecution history does apply because the specification equates the purity of intermediates and the final products and provides no reason to differentiate "substantially pure" in the two contexts. This is consistent with Judge Greenaway's preliminary injunction opinion in this same patent. Plaintiffs attempt to do so now is a post-hoc justification that is not supported in the intrinsic evidence.

a. The claims and specification show that "substantially pure" has the same meaning whether it refers to the final piperidine derivative, or the para-CPK intermediate.

Neither the claims nor the specification give sufficient guidance on the meaning of "substantially pure" or "substantially pure regioisomer of the formula" to solve the claim construction issue before the Court. The claim itself uses the word "substantially pure" with respect to para-CPK. ('791 patent, 22:59-66). The plain language of the words "substantially pure" implies that the great majority of the starting material is para-CPK. However, while this might be of assistance if the accused infringer used the para-CPK in only a 40% concentration, it is not helpful here, where all the potential infringers propose much higher concentrations.

Nonetheless, because the specification uses the same term consistently for both intermediates and derivatives, the Court finds that what "substantially pure" means when it modifies the piperidine derivative applies equally to its context in the claims' "substantially pure regioisomer of the formula."

There is a presumption in claim construction that the same words have a consistent meaning throughout the patent "unless it is clear from the specification and prosecution history that the terms have different meanings at different portions" of the patent. *PODS, Inc. v. Porta*

Stor, Inc. 484 F.3d 1359, 1364 (Fed. Cir. 2007); *see also Felix v. American Honda Motor Co., Inc.*, 562 F.3d 1167 (Fed. Cir. 2009). Here, the context does not delineate the two different usages of substantially pure; indeed the specification conflates them.

The specification does not support separate standards of substantial purity. The inventor uses the phrases "substantially pure" and "substantially pure regioisomers" indiscriminately to refer to both final products and intermediates. ('703 patent, passim). There is no evidence that the inventor intended the term to mean different things. If the inventor had intended to have separate definitions, he had ample opportunity in the specification to clarify. The fact that he did not do so only supports the presumption that the same words have a consistent meaning. *See PODS*, 484 F.3d at 1364.

Not only does the specification indiscriminately use "substantially pure" to refer to both final products and intermediates, it specifically equates them. In one important passage, when the specification is describing the prior art process, the specification uses the same "substantially pure" phrase to refer to several intermediates *and* the final product. ('703 patent, 4:15-4:25). The passage appears immediately after the patent explains the prior art chemical process ("the Carr process") for formulating piperidine derivatives, the same product this patent's claims create, and explains its draw backs. Referring to the intermediates and final product of the Carr process, the Background states:

> Although the second mixture [an intermediate] and the third mixture [the final product] of regioisomers can be analyzed by HPLC experiments, a practical separation to obtain gram quantities of substantially pure regioisomers has not been achieved.
>
> Each *mixture* (including the first [also an intermediate]), would be expected to contain 33% of the para isomer and 67% of the meta isomer. Since these components are inseparable, it has not been possible to obtain *either of the regioisomers in each mixture in substantially pure form.*

('703 patent, 4:15-25) (emphasis added). This passage uses the same "substantially pure" to refer to all the regioisomer mixtures – the first two intermediates and the final product. This shows that the patentee used the word interchangeably regardless of whether he was referring to an intermediate or a final product, so long as it is a regioisomer. Both the piperidine derivative and the para-CPK intermediate are regioisomers and therefore, the words "substantially pure" are used consistently for both. (*See* '703 patent, 4:18-24; describing intermediates and fexofenadine from the prior art process as regioisomers). Further, the passage uses the words "substantially pure" out of the context of a specific regioisomer or chemical product. The fact that the words do not appear next to or modify a specific chemical product undermines Plaintiffs' argument that the words cannot be interpreted without reference to the specific chemical product that it modifies. (JCC at 36).

This passage also informs the reader that "substantially pure," in its consistent use, means greater than 67% purity. However, again, that purity level does not solve the claim construction issues before the Court.

The specification provides no further guidance on how "substantially pure" the para-CPK intermediate must be. However, the prosecution history displays for this Court exactly what the inventor meant by the words "substantially pure" because he used them in to mean 98% purity in both the prosecution of the '703 patent and the related '610 patent, which issued prior to the '703 patent.

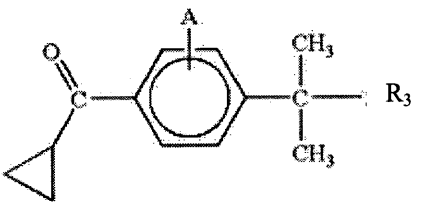
b. The prosecution histories of the '703 and the related '610 patents establish that the words "substantially pure" refer to pharmaceutical grade purity, i.e. 98% purity.

The prosecution history "can inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor [disclaimed the scope of] the

invention in the course of prosecution." *Phillips,* 415 F.3d at 1317; *see also Telcordia Techs., Inc. v. Cisco Sys.*, 612 F.3d 1365, 1372 (Fed. Cir. 2010). Indeed, statements made during the prosecution histories of related patents, even later patents, can inform the court of the intended scope of a "common term" in the two patents. *Ormoco v. Align Tech., Inc.*, 498 F.3d 1307, 1314 (Fed. Cir. 2007), *cert. denied*, 128 S. Ct. 2430 (2008); *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1349-50 (Fed. Cir. 2004) ("We take the patentee at its word and will not construe the scope of . . . [a] patent's claims more broadly than the patentee itself clearly envisioned"); *Jonnson v. Stanley Works*, 903 F.2d 812, 818 (Fed. Cir. 1990). However, to operate as a disclaimer, the statement must be clear and unambiguous and constitute a clear disavowal of scope. *Verizon v. Vonage Holdings Corp.*, 503 F.3d 1295, 1306-07 (Fed. Cir. 2007).

The prosecution history demonstrates both that the inventor understood the term "substantially pure" to mean 98% purity and that the inventor clearly and unambiguously disavowed any other claim scope. In the first application underlying the '703 patent, the examiner rejected the claims as being obvious based upon several references. In the patentee's response, he distinguished the Carr reference by using the term "substantially pure" on several occasions and equates this term with pharmaceutical grade purity:

> More particularly, the Carr terfenadine metabolite patents' product is prepared by the above-described prior art process which requires removal of a significant quantity of an impurity by recrystallization and, even after such treatment, it still contains that impurity at a level of up to 5%. By contrast, the *process of the present invention* utilizes a unique starting material, namely a *substantially pure* regioisomer of the following formula:



The patentee went on to argue:

> Unlike the prior art process, *no separation step is required after that reaction* and, even more interestingly, the product of the present process can be prepared *in a substantially pure form suitable for pharmaceutical use.*

(Karta Decl. Ex. 26 at 11-12) (emphasis added). On the next page, the patentee stated that:

> Even if a prima facie case of obviousness could be established from the combination of Carr, Sheehan, and Morrison (which it cannot), that combination is clearly rebutted by the advantageous results achieved with the process of the present invention. Here, as noted above, the prior art process for making the piperidine derivatives of the present invention produces an impure mixture which can only be partially purified to an impurity level of up to 5%. By contrast, as noted supra, the process of the present invention does not yield a product with such an impurity level and, as a result, *is able to* produce the desired piperidine derivative compounds at *a purity level suitable for pharmaceutical use.*

(*Id.* at 13) (emphasis added). These passages link the term "substantially pure" with pharmaceutical grade purity. It is essentially undisputed that pharmaceutically acceptable purity is 98%, (*See* D'Ambra Dep. at 167-68), and therefore, these passages equate 98% purity with "substantial purity."

The patentee also equates "substantial purity" with 98% purity in the prosecution history of the '610 patent, which issued prior to the '703 patent. After the '610 patent issued, the Patent and Trademark Office ("PTO") declared an interference. The portions of that interference referenced below occurred prior to issue of the '703 patent.

The disputed subject matter included claims 12-17 of the '610 patent, which use "substantially pure" to refer, not to the final pharmaceutical product (the piperidine *derivative*), but only to the para-CPK intermediate and to another piperidine *intermediate*. The disputed subject matter also included claims 1-7, which include "substantially pure" to refer to the final piperidine *derivative*. The examiner's comments made clear that the primary subject of the interference was the purity of the final product, the piperidine derivatives:

> Claims 1-7 are compound claims which correspond to the count by directly reading on or inherently disclosed based on the dehydrate disclosed by D'Ambra on Col. 22, example 10.
>
> . . . .
>
> Claims 12-17 correspond to the count because these product by process claims have the exact same attributes *in purity as the substantially pure compounds of claims 1-7* since the Declaration by Laskovics provided evidence that the regiospecific purity can be achieved by [an] alternative process. Therefore, the product by process claims *do not provide[] [any] limitation distinct from the substantially pure products of claims 1-7.*

(Karta Decl. Ex. 28 at 4-5) (emphasis added). On October 17, 1997, D'Ambra responded to the interference and stated that:

> When read in light of the specification, one skilled in the art would have understood that the phrase "*substantially pure*", as used in claim 1-17 of the D'Ambra Patent, to mean that the subject compound has *pharmaceutical grade purity* and is purer than that attained by the prior art (e.g., U.S. Patent Nos. 4,254,129, 4,254,130, 4,285,957 and 4,285,958 to Carr (collectively, "the Carr Patents"). As demonstrated, infra, those skilled in the art recognized that *pharmaceutical grade purity* requires an impurity level no greater than 2%, and the Carr Patents were unable to achieve such purity.

(Karta Decl. Ex. 30 at 3). In these prosecution histories, the patentee repeatedly refers to the term "substantially pure" as meaning pharmaceutical grade, or 98% purity. Therefore, it is clear that by "substantially pure" the patentee meant pharmaceutical grade purity, which requires an impurity level no greater than 2%. These statements both explain the meaning the patentee assigned to "substantially pure" and represent a clear disclaimer of patent scope for this patent. *Phillips,* 415 F.3d at 1317. As such, we take the patentee at his word and do not construe the claims in a manner more broadly than he himself intended.

This Court may agree with Plaintiffs that all of the prosecution history cited above focuses on the purity of the final-product piperidine derivative and not to the para-CPK intermediate: Indeed, numerous phrases such as "subject compound," "attained," "compounds of claims 1-7," "products of claims 1-7," "the product of the present process," and "is able to

produce the desired piperidine derivative compounds," make clear that the prosecution history refers to the final product and not the intermediate. However, as discussed, because the specification uses the words "substantially pure" to refer to both the final products and intermediates, this portion of the prosecution history also applies to the construction of the "substantially pure" para-CPK intermediate.

The only remaining issue is whether the para-CPK must be pure with respect to "all impurities" or only the meta-CPK isomer. The Court finds that it must be pure with respect to all impurities, but not intended elements of solutions such as solvents, catalysts, or other compounds that are not considered impurities.[2] The plain language of the term "substantially pure" is relative to all impurities – a solution of 25% para-CPK, 0.2% meta-CPK, and 74.8% dirt would not be substantially pure. Further, the passage from the background does not dictate a different result. While it speaks of purity and identifies the other regioisomer as an impurity, it does not suggest that is the exclusive impurity. It states that each mixture would "*contain* 33% of the para isomer and 67% of the meta isomer" and then comments that because this impurity cannot be isolated, neither can be obtained in substantially pure form. ('703 patent, 4:15-25) (emphasis added). Thus, ridding the mixture of the meta isomer would be necessary to achieve purity, but the passage does not suggest it would be sufficient. Further, the prosecution history distinguishes another process because of other impurities. (Karta Dec. Ex. 30, at 19, 22-24 (distinguishing based on the presence of proteins, steroids, lipids, etc.)).

Therefore, consistent with Judge Greenaway's preliminary construction in an opinion on an application for a preliminary injunction in this same patent, this Court finds that "substantially pure" means "at least 98% purity with respect to all impurities."

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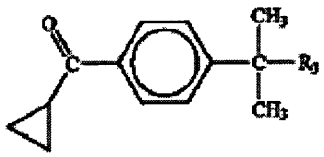
[2] Indeed, the specification discloses several catalysts, bases, and solvents for use in the process. ('703 patent, 18:50-67).

2. Terms in the '906 patent

At issue in the '906 patent are the following terms:

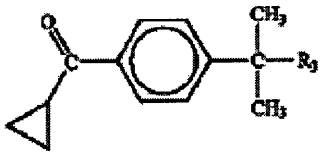
(1) "regioisomer of the following formula



"

from claim 1 of the '906 patent;

(2) "providing a regioisomer of the following formula:



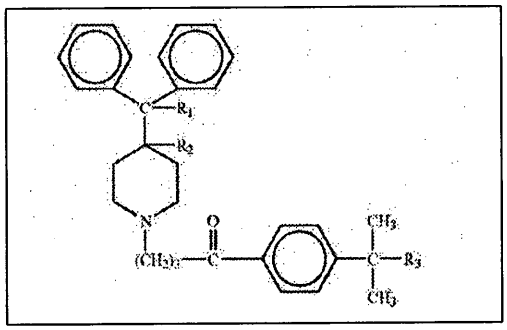
"

from the same portion of claim 1 of the '906 patent as the above term but including the word "providing" that appears before that term; and

(3) "piperidine derivative,"

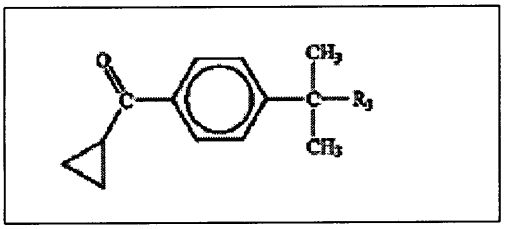
from claims 1, 6, 7, 8, and 9 of the '906 patent. The first two terms are essentially identical and the parties concede that the dispute is centered on the second term. All three terms appear in claim 1 of the '906 patent, which claims:

1. A process of preparing a *piperidine derivative* compound of the formula:

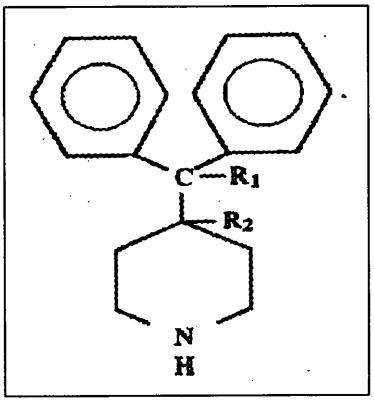


wherin

R_1 is hydrogen or hydroxyl;
R_2 is hydrogen;
or R_1 and R_2 taken together form a second bond between the carbon atoms bearing R_1 and R_2;
R_3 is – COOH or – $COOR_4$;
R_4 has 1 to 6 carbon atoms;
said process comprising;
providing a regioisomer of the following formula:



converting the regioisomer to the piperidine derivative compound with a piperidine compound of the formula:



('906 patent, 22:32-23:14) (emphasis on disputed terms). This claim is very similar to the '703 patent except that it does not require the intermediate para-CPK to be substantially pure and the aromatic rings have hydrogen substituents; it also does not require the final product piperidine derivative to be substantially pure.

a. Providing a regioisomer of the formula

Defendants argue that the same standard for substantial purity should be applied despite the lack of any such language in the claims for several reasons. First, Defendants argue that the piperidine derivative and the CPK depicted show pure para-regioisomers and not mixtures.

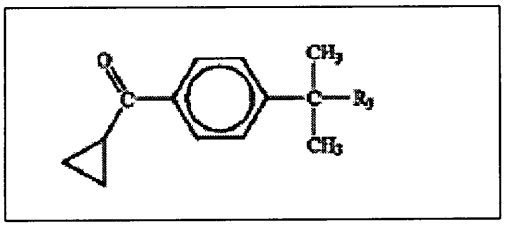
(Defs.' Br. at 10-11, 28). Second, Defendants argue that the specification's numerous statements about the scope of the invention covering only substantially pure piperidine derivatives narrows the claims terms. (Defs.' Br. at 13-19). Finally, Defendants argue that the prosecution history of this and related applications shows that the invention is limited to substantially pure piperidine derivatives and substantially pure para-CPK intermediates. Plaintiffs point to the lack of the words "substantially pure" or, indeed, any purity requirements in the claims to support the broad construction that the regioisomer must simply be "present." (JCC at 39).

This is a very close issue. However, the Court finds that the while the plain meaning of the term suggests that no particular purity is required, the specification's repeated narrowing statements make clear to the person of ordinary skill in the art that the invention is limited to substantially pure para-CPK intermediates.

1. The claim language does not require the para-CPK to contain any level of purity, other than that it be present.

The claim language here is clear. No particular level of purity is required. The language states:

providing a regioisomer of the following formula:



('906 patent, 22:60-66).

While the formula depicts only para-CPK and not a mixture, the surrounding language does not require the overall solution to be pure. The formula depicts the para-CPK regioisomer only, because, as discussed above, it has the bond in the fourth position on the benzene ring; it

also does not depict a mixture because the bond does not continue into the benzene ring. If the patentee had meant a mixture of the two, the convention in the art is that, rather than depict the bond ending at the edge of the benzene ring, the drafter would continue the bond inside the benzene ring to show that more than one isomer was present. (D'Ambra Dep. at 92; '906 patent, 2:58-67, 3:23-40, 15:1-13; *see also* '906 patent, 23:15-24:22). However, despite the fact that this depicts only the para-CPK, the plain language of the claims is open to the presence of any amount of meta-CPK or other impurities. The process claimed requires "*providing*" this regioisomer. ('906 patent, 22:60-66). Providing does not require that regioisomer be the only chemical present. If a party host tells a guest that she will be providing the alcohol for the party, the guest will not believe she lied when she has both alcohol and food at the party. Simply put, "providing" does not require exclusivity; one chemical may be provided in a mixture even if others are present. Thus, the ordinary meaning of the term does not require *any* purity whatsoever.

This conclusion is also bolstered when this Court compares the language of this claim to that of the '703 patent.[3] The '703 patent requires "substantially pure" regioisomer, which shows that when the patentee intended this term to be limited to substantial purity, he knew how to do so. ('703 patent, 24:8-19). The '906 patent, which issued after the '703 patent starkly omits that limitation. Therefore, the plain language of this patent shows that "providing" the depicted regioisomer does not require any specified purity. However, the specification's repeated statements that the invention is limited to substantially pure regioisomers overcomes this plain language.

[3] The Court does not rely upon claim differentiation between claim 3 and 1 of the '906 patent because the claims have a different scope regardless of the purity of the para-CPK intermediate. Claim 3 contains several additional steps for what "providing" means. Even if claim 1 required providing a pure para-CPK intermediate, these additional steps that constitute the "providing" would differentiate the claims.

2. *The specification limits the invention to the use of substantially pure regioisomers.*

The specification makes this a difficult issue because portions of the specification describe the invention as one that produces "substantially pure" piperidine derivative and even where it mentions piperidine derivatives that are not substantially pure, the specification discloses that they are made using substantially pure para-CPK.

While the claims define the invention, the intrinsic evidence's description of the invention as a whole can inform a court that a term's construction should be narrower than the meaning of the term in isolation. *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1318 (Fed. Cir. 2006); *see also Telecordia Tech., Inc., v. Cisco Sys., Inc.*, 612 F.3d 1365, 1374 (Fed. Cir. 2010). The specification may narrow this meaning because the "claims must be read in light of the specification" and because the specification is "the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315. If the patentee uses the specification to broadcast to the public that the invention is limited to a construction that is more narrow than the normal meaning of the claims, "the public is entitled to take the patentee at his word." *Honeywell*, 452 F.3d at 1318. Thus, where the specification makes statements about the entirety of the invention, and not just the embodiments of the invention, those statements can limit the scope of the claims. *See TiVo v. EchoStar Commc'ns Corp.*, 516 F.3d 1290, 1300-1301 (Fed. Cir.), *cert. denied*, 129 S. Ct. 306 (2008).

For example, in *Honeywell*, the patentee described "this invention" or "the present invention" as a fuel filter on four occasions in the specification. 452 F.3d at 1318. Specifically, the specification used several phrases like "This invention relates to a fuel filter." *Id.* The Federal Circuit found that these statements limited the invention to fuel filters despite the fact that the claim language could be interpreted more broadly. *Id.* at 1318-19. In doing so, the

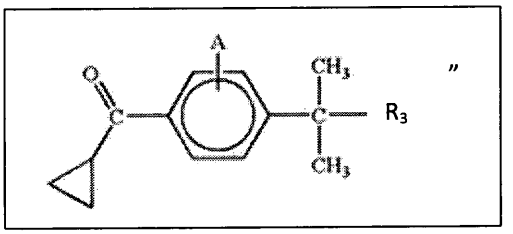
Federal Circuit was not swayed by the fact that the prosecution history contained a passage that suggested a broader interpretation by the patentee. *Id.*

However, in *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244 (Fed. Cir. 2008), the court found that the specification's statements did not limit the invention. In *Halliburton* statements in the specification characterized "the invention" as omitting clay and others stated that the invention did not need organophilic clay. The Federal Circuit found that, despite the invention being described as omitting clay, the fact that other passages that stated that there was "no need" for organophilic clay and that "preferably" none of the clays were added suggested that these statements described preferred embodiments and did not limit the scope of the invention. *Id.* at 1250-51.

In this case, several statements in the specification do state that the invention is limited to producing "substantially pure" fexofenadine. Several statements in the specification refer to "the invention" as relating to "substantially pure piperidine derivative compounds of the formula . . . ." The beginning of the Abstract, the Summary of Invention, and Detailed Description of the Invention all use similar language. ('906 patent, Abstract, 4:28-30, 6:3-5). These statements do not refer to embodiments. Indeed, this is the same language that the *Honeywell* court used to limit the scope of the claims and it suggests that the final product must be substantially pure.

[redacted] (*see* D'Ambra Dep. at 142-143), this suggests the para-CPK must also be substantially pure. In addition, except when describing the background of the art, every time the para-CPK is depicted in the specification it is mentioned as "substantially pure." (*See* '906 patent, passim).

Further, even to the extent that the specification uses the term "piperidine derivative" without the words "substantially pure" to modify it, the specification limits the preparation of these piperidine derivatives to substantially pure para-CPK. Column 11 points out in the Detailed Description of the invention that "the piperidine derivative compounds *of the present invention are prepared* by providing a *substantially pure regioisomer of the following formula*:



"

('906 patent, 11:33-46; *see also* 5:5-20 and surrounding context). This relates even the less than substantially pure piperidine derivatives *of the invention* to the substantially pure regioisomer. (*See also* '906 patent, 5:5-16 and 34-37). Again this refers to the invention and does not says that they "optionally" can be prepared, it says they "are prepared." Indeed, the importance of purity of the para-CPK is such that the specification provides three different methods for producing substantially pure para-CPK and dedicates a large portion of the specification to the task. ('906 patent, 11:66-15:25) Thus, the invention is prepared using the substantially pure regioisomer.

Plaintiffs' citation to numerous places where the specification refers to piperidine derivatives without a purity modifier correctly demonstrates that not all piperidine derivatives of the invention need be substantially pure. (*See e.g.* '906 patent, 1:26-27 (Field of Invention), 5:5-30, 5:34-55, 10:9, 10:44; 15:20-25). The Court agrees that this prevents those compounds from being strictly so limited. However, as discussed, even those impure piperidine derivatives are prepared using substantially pure para-CPK. Further, while the examples do not have purity

requirements for the para-CPK, as both the inventor and Plaintiffs expert have conceded, they provide processes for purifying the para-CPK if taken in sequence as Plaintiffs' expert suggests they would be. (Barrett Tr., May 27, at 59-60; Barrett Supp. Decl. May 10, 2010 at ¶39; D'Ambra Dep. at 154-56). Thus, when read in light of the specification's numerous statements that limit the scope of the invention, the Court reads them as creating and using substantially pure para-CPK.

Thus, like in *Honeywell*, the patentee has limited his invention through the specification's statements about what "the invention" constitutes. Here that limits the invention to the use of "substantially pure" para-CPK intermediates.

3. The prosecution history does not provide additional support for any party's position.

Defendants cite the prosecution history of earlier patent applications to show that the '906 patent application is limited to producing substantially pure fexofenadine and using a substantially pure regioisomer. Most of that prosecution history is set forth above in the discussion of the '703 patent.

However, the controlling law establishes that arguments made in prior applications do not apply when the claim terms in subsequent applications are omitted or are different than those to which the disclaimers were made. *Saunders Group, Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 133-34 (Fed. Cir. 2007). All of this prosecution history relates to fexofenadine and intermediates that are "substantially pure" or centers around discussions of purity. Those terms are not used in the claims in the '906 patent and so the prosecution histories are irrelevant.[4] *See id.* The remaining citation to the November 13, 2007 response to the office action is also not helpful. It merely states that the scope of the '906 patent is more limited because it restricts the aromatic

[4] Using the specification to imply this term into the claims and then using the prosecution history to support it would be bootstrapping.

rings to having hydrogen substituents, and not the several other groups that are available in the '703 patent. It does not explicitly say that the scope is more limited in all ways, though this may be one possible interpretation of the passage. (*See* Kim Decl. Ex. 16 at 10). Thus, the prosecution history provides no additional support for the position of either party.

Thus, because the specification limits the plain language of the term "providing a regioisomer of the formula," the court construes "providing a regioisomer of the formula" as "providing the regioisomer having the structure shown in the formula (having at least 98% purity)."

b. Piperidine derivative

The next term at issue, is the term "piperidine derivative" in claims 1, 6, 7, 8 and 9. The dispute of the parties is again centered on the purity of the derivative. Plaintiffs assert that there is no purity required of the piperidine derivatives and submit several constructions that differ only in the slightly different chemical diagrams that occur in the various claims. (JCC at 49-51). Defendants again argue that a specific purity is required of the piperidine derivative. (*Id.*). However, the plain language of the term does not require any specific purity and the specification and the prosecution history do not require such purity either.

First, the context of the term simply states that it is a "process of *preparing* a piperidine derivative compound of the formula." Preparing something does not require that it be the exclusive thing that is prepared. The words "substantially pure" are not used in the claims as they are in other portions of the specification, suggesting that the claims did not intend substantial purity to apply. (*See* '906 patent, 22:33-50, 24:30-48, 25:35-50).

Second, as discussed in the previous term, while it comes close, the specification does not limit the invention to the preparation of substantially pure piperidine derivatives. As discussed

above, several examples of the term piperidine derivative appear without the requirement that it need to be substantially pure.[5] While the context of these terms may suggest that some refer to substantially pure piperidine derivatives and unlike *Halliburton*, no portion of the specification implies substantially pure derivatives are merely embodiments, the Court finds that the specification also discloses other non-purity limited piperidine derivatives.

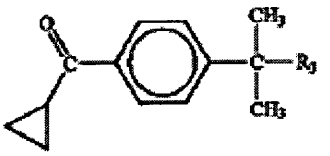
Third, as discussed, the prosecution history does not apply to this claim because the limitations discussed in the prosecution history are omitted from this claim. *See Saunders Group, Inc.*, 492 F.3d at 133-34. Consequently, this Court does not find that the term is limited to substantial purity and construes the term "piperidine derivative" in line with its plain meaning, which is "a piperidine derivative compound having the structure shown in the formula."

III. Conclusion

For the foregoing reasons the Court construes the terms in the '703 patent and the '906 as follows:

(1) "substantially pure," means "at least 98% purity with respect to all impurities";

(2) "providing regioisomer of the following formula



"

means "the regioisomer having the structure shown in the formula is present in at least 98% purity with respect to all impurities"; and

(3) "piperidine derivative," means "a piperidine derivative compound having the structure shown in the formula."

[5] Their preparations are limited to the use of substantially pure para-CPK, but they are nonetheless part of the invention.

The construction of these terms makes the construction of the other terms unnecessary.

Dated: January 13, 2011

/s/ Garrett E. Brown, Jr.
GARRETT E. BROWN, JR., U.S.D.J.